



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 8, 1999

Cerie B. McDonald, President
Mikart Incorporated
1750 Chattahoochee Avenue, N.W.
Atlanta, GA 30318

Dear Mr. McDonald:

Your petition requesting the Food and Drug Administration to determine whether Carbinoxamine Maleate 4 mg/5 cc Elixir (NDA 8-955) was withdrawn from sale for reasons of safety and effectiveness was received by this office on October 26, 1999. It was assigned docket number 99P-4648/CP 1. The docket number has been changed to 99P-4848/CP 1. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lyle D. Jaffe", is written over the typed name.

Lyle D. Jaffe
Dockets Management Branch

99P-4848

ACK1